IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1632
Image

In re Patent Application of

Atty Dkt. 3665-21
C# M#

SALOMON, B. et al.

Group Art Unit: 1632

Serial No. 10/067,503

Examiner: WILSON

Filed: February 7, 2002

Date: October 14, 2003

Title: CELL THERAPY USING IMMUNOREGULATORY T-CELLS

OIPE JC25 OCT 14 2003 PATENT & TRADEMARK OFFICE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

☒ **Correspondence Address Indication Form Attached.**

Fees are attached as calculated below:

Total effective claims after amendment **0** minus highest number previously paid for **20** (at least 20) = 0 x $ 18.00	$	0.00
Independent claims after amendment **0** minus highest number previously paid for **3** (at least 3) = 0 x $ 86.00	$	0.00
If proper multiple dependent claims now added for first time, add $290.00 (ignore improper)	$	0.00
Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) ($110.00/1 month; $420.00/2 months; $950.00/3 months)	$	0.00
Terminal disclaimer enclosed, add $ 110.00	$	0.00
☐ First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) ($770.00) ☐ Please enter the previously unentered , filed ☐ Submission attached	$	0.00
Subtotal	$	**0.00**
If "small entity," then enter half (1/2) of subtotal and subtract ☐ Applicant claims "small entity" status. ☐ Statement filed herewith	-$	0.00
Rule 56 Information Disclosure Statement Filing Fee ($180.00)	$	0.00
Assignment Recording Fee ($40.00)	$	0.00
Other: Response		**0.00**
TOTAL FEE ENCLOSED	$	**0.00**

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON & VANDERHYE P.C.
By Atty: B. J. Sadoff, Reg. No. 36,663

Signature: _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

SALOMON, B. et al. Atty. Ref.: 3665-21

Appl. No. 10/067,503 Group: 1632

Filed: February 7, 2002 Examiner: WILSON

For: CELL THERAPY USING IMMUNOREGULATORY T-CELLS

* * * * * * * * * * * *

October 14, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE

Responsive to the Official Action dated September 11, 2003, the applicants elect, with traverse, the subject matter of the Examiner's Group I for further prosecution in the above.

Reconsideration and withdrawal of the restriction requirement, at least with regard toto the Examiner's Groups I and II, are requested and consideration of the following in this regard is requested.

The applicants have elected the subject matter of the Examiner's Group I, i.e., claims related to a method of treating an immune disease using non-genetically altered T-cells that suppress a pathological immune response (claims 1-14, and 16). The Examiner has asserted that claims drawn to a method of treating an immune disease using genetically altered T-cells that suppress a pathological immune response however

are separately patentable. See, Examiner's Group II. The basis of the restriction between Groups I and II is that, according to the Examiner, "non-genetically modified cells suppress the pathological immune response... while genetically modified cells in Group II deliver proteins not produced by the T-cells that suppress the pathological immune response." See, page 2 of the Office Action dated September 11, 2003 (Paper No. "090803"). The Examiner also states at page 6 of Paper No. "090803" that restriction is proper because the subject matter of the separate Groups have acquired a separate status in the art because of their recognized divergent subject matter, as apparently supported by the Examiner's classification of the subject matter of Group I in Class 424, subclass 93.7 and the subject matter of Group II in Class 424, subclass 93.2.

Initially, the applicants note that while the subject matter of the Examiner's Group II relates to methods of treating an immune disease using genetically altered T-cells that suppress a pathological immune response, the recited treatment of the methods of both the Examiner's Groups I and II is due to an amount of immunoregulatory T-cells effective at suppressing a pathological immune response. Such T-cells effective at suppressing a pathological immune response can be further genetically modified, as recited in the Examiner's Group II. The genetic modification of the Examiner's Group II is used to increase the efficiency of immunoregulatory T-cells. See, for example, page 12, line 18 to page 13, line 6 of the specification. It is thus believed that using non-genetically altered immunoregulatory T-cells or genetically modified immunoregulatory T-cells constitutes a single invention which should be examined in the same application.

Accordingly, the Examiner's basis for the restriction requirement, at least with regard to the Examiner's Groups I and II, is submitted to not support maintaining the restriction requirement. Withdrawal of the restriction requirement, at least with regard to the Examiner's Groups I and II is requested.

As for the Examiner's assertion relating to a recognized separate status in the art for the indicated Groups of claims, the applicants note that the following 37 patents have issued wherein Class 424, subclasses 93.7 and 93.2, i.e., those indicated in the Examiner's Group I and II, were searched, as evidence of the overlapping nature of this subject matter.

Searching 1976 to present...
Results of Search in 1976 to present db for:
CCL/"424/93.7" AND CCL/"424/93.2": 37 patents.
Hits 1 through 37 out of 37

	PAT. NO.	Title
1	6,613,320	Defective CD4+T-cells that express active CD40-L
2	6,613,319	Long-term expression of erythropoietin and growth hormone by transforming muscle cells
3	6,569,421	Treatment of brain damage
4	6,538,174	Animal model for transplantation
5	6,465,247	Mammalian myeloid progenitor cell subsets
6	6,461,865	Calreticulin-deficient cells
7	6,451,305	Methods for stimulating T cell responses to tumor cells expressing LFA-3 and a CD28 or CTLA4 ligand
8	6,403,080	Methods of modulating an immune response to antigen, and cells for use in the method
9	6,387,369	Cardiac muscle regeneration using mesenchymal stem cells
10	6,338,845	Tumor killing effects of enterotoxins, superantigens, and related compounds
11	6,328,969	Method and compositions for stimulation of an immune response to a differentiation antigen stimulated by an altered differentiation antigen
12	6,326,465	Immunomodulatory polypeptides derived from the invariant chain of MHC class II

13 6,299,873 Method for improvement of radiation therapy of malignant tumors
14 6,264,943 Method for transplanting cells into the brain and therapeutic uses therefor
15 6,251,385 Method of cancer treatment
16 6,225,119 Production of megakaryocytes by the use of human mesenchymal stem cells
17 6,221,351 Tumor killing effects of enterotoxins, superantigens, and related compounds
18 6,184,032 Identification of genes encoding cell surface antigens using CREF-Trans 6 cells
19 6,132,718 Multi-stage cascade boosting vaccine
20 6,068,836 Cell compositions for use in transplantation
21 6,048,725 Recombinant human immunodeficiency virus producing cell lines
22 5,912,236 Broad-spectrum tumor suppressor genes gene products and methods for tumor suppressor gene therapy
23 5,869,037 Adenoviral-mediated gene transfer to adipocytes
24 5,858,354 Repopulation of testicular Seminiferous tubules with foreign cells, corresponding resultant germ cells, and corresponding resultant animals and progeny
25 5,827,516 Immunomodulatory peptides
26 5,820,856 Modified TALL-104 cells to treat cancer
27 5,792,900 Compositions and methods for producing and using homogenous neuronal cell transplants
28 5,759,536 Use of fas ligand to supress T-lymphocyte-mediated immune responses
29 5,705,150 Antigen specific plasmacytomas and antibodies derived therefrom
30 5,702,702 Modified cytotoxic tall cell line and compositions and methods for manufacture and use thereof as therapeutic reagents for cancer
31 5,690,927 Use of neuro-glial fetal cell lines for transplantation therapy
32 5,683,690 Modified cytotoxic tall cell line and compositions and methods for manufacture and use thereof as therapeutic reagents for cancer
33 5,656,481 Compositions and methods for the delivery of biologically active molecules using cells contained in biocompatible capsules
34 5,653,975 Compositions and methods for the delivery of biologically active molecules using cells contained in biocompatible capsules
35 5,487,889 Bandage for continuous application of biologicals
36 5,342,776 Avian hemopoietic progenitor cells
37 4,409,331 Preparation of substances with encapsulated cells

The applicants believe the Examiner's search of the subject matter of of Gruop I will include a search of the subject matter of the Examiner's Group II. Moreover, the applicants assume that if the Examiner maintains the restriction requirement then art

teaching the method of, for example, claim 5 of the present application, would not anticipate or make obvious the subject matter of, for example, claim 1 wherein the immunoregulatory T cells might not be genetically modified. The Examiner is requested to comfirm as much in his next Action.

Reconsideration and withdrawal of the restriction requirement, at least with regard to the Examiner's Gruops I and II, are requested.

An early and favorable Action on the merits of the claimed invention is requested.

Respectfully submitted,

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